

## REMARKS

Applicants would like to thank the Office for the substantive review given to this case. Applicants would further like to note that the current Office Action does not address all pending claims. Per the Restriction Requirement issued July 22, 2008 and the Response filed August 15, 2008, Invention I (i.e., claims 1-42 and 51-54) was elected for consideration. Specifically, the Office Action does not address claims 51-54. Accordingly, Applicants request that the Office provide any comments to claims 51-54 in a subsequent non-final Office Action, if necessary. Otherwise, Applicants respectfully request notification of allowance of claims 51-54. The Applicants will address the rejections contained in the Office Action below.

In the non-final Office Action, the Office rejected claims 1-42. More specifically:

- Claims 1-42 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter;
- Claims 11, 15 and 21 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention;
- Claims 1, 7-21, 23-25 and 29-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0042725 (Mayaud) in view of U.S. Patent Application Publication No. 2004/0049506 (Ghouri) and Applicants' Own Admission;
- Claims 2-6, 26, 27 and 41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, Applicants' Own Admission and U.S. Patent No. 6,438,407 (Ousdigian);
- Claims 22, 28 and 37-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, Applicants' Own Admission and Official Notice;
- Claim 42 is rejected under 35 U.S.C. §103(a) as being unpatentable over Mayaud in view of Ghouri, AOA, Ousdigian and Official Notice.

Claims 1, 11, 14, 15, 21 and 33 have been amended. No new matter has been added as a result of these amendments. Upon entry of this Amendment and Response, claims 1-42 and 51-54 will remain pending. For the reasons set forth hereinbelow, Applicants request that the rejections associated with the pending claims be withdrawn.

**Rejections under 35 U.S.C. §101**

The Office rejected claims 1-42 under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claim 1 has been amended to include reference to a computing device. Accordingly, Applicants respectfully request that the rejections of claims 1-42 under 35 U.S.C. §101 be withdrawn for at least this reason.

**Rejections under 35 U.S.C. §112, ¶ 2**

The Office has rejected claims 15 and 21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office stated that claims 15 and 21 recite the term “effective,” which is determined to be vague and indefinite. Claims 14, 15 and 21 have been amended to remove this term.

The Office has further rejected claim 11 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office stated that claim 11 included the term “optionally,” which is determined to be open conditional language that causes the limitation to be omitted. Claim 11 has been amended to remove the phrase “and optionally identifying subprocesses of said one or more processes.”

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §112, ¶2, be withdrawn.

**Claims 1-42**

Applicants submit that independent claim 1 is nonobvious over Mayaud in view of Ghouri and Applicants’ Own Admission (AOA) because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of claim 1. *See* MPEP §2143 (stating that one of the elements of a *prima facie* case of obviousness under §103(a) is that the prior art references must teach or suggest all the claim limitations). More particularly, Applicants submit that the combination of Mayaud, Ghouri and AOA fails to teach or suggest the combination of at least the following limitations of claim 1:

- identifying a medication-use process associated with a pharmaceutical product; and

- identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects.

Mayaud discloses a wirelessly deployable, electronic prescription creation system for physician use that captures a patient condition and treatment objective into a prescription and provides a patient record assembly with privacy controls, adverse indication review, and online access to drug information. *See* Mayaud at Abstract. Mayaud further describes a condition selection which identifies a patient condition and enables a drug to be selected for such condition by a physician. *See id.* at [0269]-[0270].

Ghouri discloses a system and method for electronic and algorithmic data mining of an individual physician's prescribing history to determine the approximate distribution of diseases within their practice population for optimizing pharmaceutical sales and marketing. *See* Ghouri at Abstract. Ghouri discloses comparing one drug against competitor drugs by determining drug-drug, drug-disease, and drug-allergy interactions for a plurality of drugs, and determining a safety score for each interaction based on the severity and an expected frequency of the interaction. *See id.* at [0084].

In contrast, claim 1 requires identifying a medication-use process associated with a pharmaceutical product. A medication-use process includes a plurality of steps, such as identifying a condition, prescribing a drug, filling out a prescription, administering the prescribed drug and monitoring a patient's reaction to the prescribed drug. In contrast, Mayaud merely discloses a prescribing operation based on a determined condition. Mayaud does not identify a medication-use process as is described in reference to claim 1. Moreover, Ghouri does not describe any medication-use process. Ghouri is directed to determining drug interactions between competitor drugs to determine which drug has the least severe and/or least common side effects. Ghouri does not teach or suggest identifying a medication-use process as described in claim 1.

Claim 1 further requires identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects. The Office does not assert that either Mayaud or Ghouri teaches or discloses identifying potential failure modes where the medication-use process will not be adequate. This is because neither Mayaud nor Ghouri teaches identifying potential failure modes. Rather, the Office depends on paragraphs [0002]-[0006] of Applicants' specification for such limitation. However, these

paragraphs of Applicants' specification do not teach or suggest identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects. Such paragraphs merely teach risk management strategies and programs that have been used to assess risk in industries including manufacturing, environmental, food industries and aviation. Nothing in these paragraphs teaches or suggests the use of such to identify failure modes related to a medication-use process.

Therefore, for at least the reasons set forth hereinabove, Applicants submit that claim 1 is nonobvious over the combination of Mayaud, Ghouri and AOA because the cited references fail to teach or suggest each and every limitation of claim 1. *See* MPEP §2143. Applicants further submit that claims 2-42, which depend from and incorporate all of the limitations of claim 1, are also nonobvious over the cited references. *See* MPEP §2143.03 (stating that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious). Accordingly, Applicants request that the rejections associated with claims 1-42 be withdrawn.

#### **Claims 51-54**

As stated above, the Office has not addressed claims 51-54 in the Office Action. Applicants request notification of allowance of these claims. If the Office intends to reject such claims, Applicants respectfully request that such rejections be submitted in a subsequent non-final Office Action so that Applicants may have a chance to respond to such rejections.

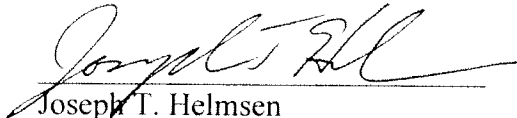
All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. There being no other rejections, Applicants respectfully request that the current application be allowed and passed to issue.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, I invite the Examiner to telephone me directly.

### AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment and Response, or credit any overpayment, to deposit account no. 50-0436.

Respectfully submitted,  
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